

S or A, X at positions 4, 6, 7, 8, 9, and 10 are any amino acid, and X at position 5 is L or I.” The P.T.O. asserted that this definition did “not meet the requirement that each amino acid be specified without ambiguity” as “the exact identity of each amino acid in the sequence must be defined.”

By way of response, applicants provisionally elect to prosecute the claims of Group I (Claims 1, 8-13, 20-29, 36-41, and 48-52), with traverse. Applicants further provisionally elect, with traverse, the single amino acid sequence LSQELAIPYEE.

Under the controlling legal standard, restriction under 35 U.S.C. § 121 of the subject matter of a single claim is improper and impermissible. The Court of Customs and Patent Appeals extensively discussed and decided this issue in *In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328 (C. C. P. A., 1978) (“*Weber*”). In that case, the Court stated that

[a]s a general proposition, an applicant has the right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant to eventually have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim...

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be “independent and distinct.” It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular *claim* on the same basis.

Id. at 331-332 (emphasis in the original). The same court also held that refusal to act on a claim in restriction practice in fact amounts to a rejection in *In re Haas*, 179 U.S.P.Q. 623, 625 (C.C.P.A. 1973). As the foregoing excerpt from *Weber* explains, § 121 does not provide a basis for rejecting a particular claim. *See Weber* at 332. Accordingly, § 121 does not empower the P.T.O. to refuse to examine a single claim on the merits simply because the P.T.O. asserts that the claim is drawn to independent and distinct inventions. Rather, the “basic right of the applicant to claim his invention as he chooses” under § 112 is “paramount” over the P.T.O.’s right to control “such administrative matters as examiner caseloads and amount of searching done per filing fee.” *See Weber* at 332.

Group I contains four independent claims, Claims 1, 13, 29, and 41, each of which recites a method for reverse transcribing an RNA, comprising, among other elements, providing a mutant thermoactive DNA polymerase characterized in that in its native form, the polymerase comprises the amino acid sequence SEQ ID No: 1, wherein amino acid at position four of the amino acid sequence is mutated in comparison to the native sequence to an amino acid other than E, A, G, or P. Each of these independent claims is affected by the P.T.O.’s renewed Restriction Requirement.

Restriction of the subject matter of a single claim is improper for several reasons. To begin with, restriction within a single claim amounts to a rejection on the basis of 35 U.S.C § 121 as specifically forbidden by *Weber* and *Haas*. These cases unambiguously and authoritatively hold that § 121 simply does not empower the P.T.O. to refuse to consider a single claim on the grounds that it is drawn to independent and distinct inventions. Thus, refusal to consider each of Claims 1, 13, 29, and 42 as filed constitutes an improper rejection on the basis of § 121 in direct contravention of the settled law.

Under the standard of *Weber*, Applicants have the right to have each claim examined on the merits. Restriction within, for example, Claim 1 and concomitant dispersal of the claimed subject matter to separate claims ends the investigation of patentability of Claim 1 before it begins. To be patentable, a claim must satisfy the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. As discussed above, there is no basis for rejecting a claim under § 121. *See Weber* at 332. If the subject matter of Claim 1 is dispersed to multiple fragmentary claims, then it will never be determined whether Claim 1 comports with §§ 101, 102, 103,

and 112 and is otherwise patentable. Thus, restriction within a single claim denies Applicants their right to have each claim considered on the merits.

Restriction within any of these single claims to a single species, each reciting a particular mutant thermostable DNA polymerase, also does not allow Applicants to claim their invention as they define it under 35 U.S.C. § 112. While restriction of a number of claims to different applications does not affect this right, restriction within a claim vitiates Applicants' prerogative to claim their invention as they choose. Applicants have defined their invention to be, for example, the subject matter recited by Claim 1. If the Restriction Requirement is imposed and the subject matter of Claim 1 is dispersed to many claims, the P.T.O. would define Applicants' invention, as unambiguously prohibited in *Weber*. Further, restriction within a single claim improperly limits the scope of Applicants' invention as claimed in view of their description of the invention. Applicants have described a genus of mutant thermostable DNA polymerases that can be used to practice the methods of the invention. Under 35 U.S.C. § 112, Applicants are entitled to patent protection commensurate with their disclosure. Accordingly, restriction within a single claim is improper as it denies Applicants the right to claim their invention as they choose.

In addition, the totality of the resulting fragmentary claims following restriction within Claim 1 would not be the equivalent of original Claim 1 as cautioned by *Weber*. If Claim 1 is internally restricted, Applicants would be forced to prosecute fragments of Claim 1, each drawn to a particular species of mutant thermostable DNA polymerases, in a number of applications. Even if Applicant pursued this course, the scope of coverage of the resulting fragmentary claims would not be likely to be equivalent to original Claim 1. Thus, restriction within Claim 1 improperly limits the scope of Applicants' invention to individual species of mutant thermostable DNA polymerases in view of Applicants' description of a genus of mutant thermostable DNA polymerases.

Finally, restriction within a single claim places an enormous burden on Applicants in achieving patent protection of the invention as currently claimed. If Applicants are restricted to individual species of particular mutant thermostable DNA polymerases, Applicants would need to prosecute a vast number of applications, each directed to an individual species, to obtain equivalent coverage. It is unreasonable for the P.T.O. to require Applicants to

prosecute thousands to millions of applications when the P.T.O. has established procedures that minimize the burden on the P.T.O. in examining generic claims.

Applicants respectfully submit that the proper procedure for reducing the administrative burden on the P.T.O. when examining a generic claim is Election of Species. According to this practice, Applicants elect a species upon which the generic claims read in order to facilitate examination of such claims. Where both generic and specific claims are presented in an application, election of species to facilitate the examination of the generic claims is proper. *See* M.P.E.P. § 808.01(a). Even where no specific claims are presented, election of species is proper when examination of the generic claims would require an unduly extensive or burdensome search. *See id.*

Accordingly, Applicants propose to elect a species encompassed by the generic claims to facilitate prosecution on the merits. *See id.* Should the P.T.O. conclude that an Election of Species is in fact proper, Applicants could, for example, elect the species of methods for reverse transcribing a RNA in which the mutant thermoactive DNA polymerase comprises an amino acid sequence that is SEQ ID No: 3, wherein the amino acid at position 4 of said amino acid sequence is mutated in comparison to said native sequence to an amino acid other than E, A, G, P, Q, or D, and the reaction mixture is treated at a temperature between 40° C and 80° C, to facilitate prosecution on the merits.¹ Should Applicants elect this species, Applicants believe that Claims 1-3, 8-15, 20-31, 36-43, and 48-52 would read upon the elected species.

Such an election of species would reduce the administrative burden on the P.T.O. while preserving Applicants' right to claim their invention as they choose. Therefore, Applicants respectfully request that the outstanding Restriction Requirement be withdrawn.

As shown by the foregoing discussion, the Restriction Requirement imposed by the P.T.O. communications of April 24, 2002 and June 13, 2002 does not comport with 35 U.S.C § 121, 37 C.F.R. §1.141, and M.P.E.P. §§ 800 *et seq.* In accordance with the proper procedures, Applicants stand ready to elect a species to facilitate examination of the generic, subgeneric, and specific claims of the instant application. Accordingly, Applicants

¹Applicants intend only to provide an example of a species which could be elected to facilitate prosecution of the instant application. Applicants reserve the right to elect this or another species should the P.T.O. substitute an Election of Species for the outstanding Restriction Requirement.

respectfully request reconsideration of the Restriction Requirement pursuant to 37 C.F.R. § 1.143.

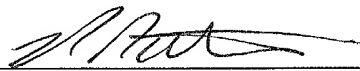
CONCLUSION

Applicants submit that Claims 1-52 satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly solicited.

No fee in addition to the Extension Fee is believe due in connection with this response. However, the Commissioner is authorized to charge any required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150 (order no. 1803-343-999).

Respectfully submitted,

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Rahul Pathak 42,983
(Reg. No.)

For: Nikolaos C. George (Reg. No. 39,201)
PENNIE & EDMONDS LLP
3300 Hillview Avenue
Palo Alto, CA 94304-1203
(650) 493-4935